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EXAMINER
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FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/692,064

Applicant(s)

DAVENPORT ET AL.

Examiner

Michele Flood

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8/28/2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-21 and 46-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-21 and 46-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/23/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/27/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group IV, Claims 18-21, in the reply filed on May 3, 2006 is acknowledged. Applicant's election without traverse of the species (a nutraceutical composition comprising glucosamine sulfate 2KCl; dry powder dosage form; a combination of an oil cake component, an acid component, a mineral component, and a functional food component; soybean flower; ascorbic acid and sodium ascorbate; a combination of zinc, boron, chromium and manganese; amino acid chelate; a combination of biotin, thiamine HCl and folic acid; symbiotic; and, N-acetyl-D-glucosamine) in the reply filed on August 28, 2006 is acknowledged. Acknowledgment is made of Applicant's consideration that Claims 18, 21, 46-50 and 60-62 are generic.

The elected species was not found; and, therefore, the claims were examined until the next species was found.

**Claims 18-21 and 46-62 are under examination.**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 48, 49, 52, 53, 56, 58 and 60-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 19, line 4, recites the abbreviation "2KCL"; Claim 19, line 3, recites the abbreviation "NaCl"; Claim 19, line 3, recites the abbreviation, "Poly-Nag."; Claim 48 and Claim 49, line 2, recite the abbreviation "g"; and, Claims 58, 60 and 61 recite the abbreviation "pbw". Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter. Appropriate correction is required.

Claim 52 recites an improper group because it recites the terms "pizza", "ranch", and "taco"; and, therefore it is unclear as to the subject matter to which Applicant intends to direct the instantly claimed invention. M.P.E.P. 803.02 states that "Since the decisions in *in re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish*, 631, F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ 2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the term "soy flower" is not congruent within the context of the other components comprising the recited Markush group, since "soy flower" is generally not defined as an "oil cake component". Applicant is invited to consult any dictionary published to obtain a definition of the terms.

The metes and bounds of Claim 53 are rendered uncertain by the phrase "wherein said acid component is ascorbic acid and at least one derivative thereof, lipoic

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acid, or dihydrolipoic acid” because it is unclear as to whether the acid component must comprise both ascorbic acid and at least one derivative thereof or either of the other, since the recitation of the claim is not set forth in terms of the alternative, with regard to the claim limitation of lipoic acid which follows the recitation of the aforementioned phrase. The lack of clarity renders the claim ambiguous.

Claim 58 recites the limitation “the selected components” in line 1. There is insufficient antecedent basis for this limitation in the claim.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

### ***Claim Objections***

Claim 52 is objected to because of the following informalities: There is an apparent misspelling in Claim 52, line 2. Applicant may overcome the objection by replacing “flower” with flour.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19, 21, 46-49 and 61 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims are drawn to a product of nature, namely poly-N-acetylglucosamine (poly-NAG). See U.S. Patent No. 6,117,851, wherein Sherman et al. teach, “Poly-NAG is a polysaccharide,

also known as chitin, which form the cell walls of fungi and the hard cells of insects and crustaceans," in Column 4, lines 62-64.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 18-21 and 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Rovati (A\*), Schleck et al. (B\*), Maier et al. (N) and Sherman et al. (C\*).

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Applicant claims a nutraceutical composition comprising a glucosamine component such that when administered to a mammal in an effective amount, the nutraceutical composition is effective to improve fertility. Applicant further claims the composition of claim 18 wherein the glucosamine component is selected from the group consisting of glucosamine sulphate, glucosamine sulfate 2KCL, glucosamine sulfate NaCl, glucosamine hydrochloride, N-acetylglucosamine, Poly-Nag glucosamine, and combinations thereof. Applicant claims a nutraceutical composition comprising a glucosamine component such that, when administered to a mammal in an effective amount, the nutraceutical composition is effective to improve fertility. Applicant further claims the composition of claim 18 wherein the glucosamine component is selected from the group consisting of glucosamine sulphate, glucosamine sulfate 2KCl, glucosamine sulfate NaCl, glucosamine hydrochloride, N-acetylglucosamine, Poly-Nag glucosamine, and combination thereof; in a dosage form selected from the group consisting of solid dosage form, dry powder dosage form, liquid dosage form, and combinations thereof; wherein the mammal is selected from the group consisting of human, bovine, equine, caprine, ovine, and porcine; wherein the composition improves fertility by achieving treatment, repair, or increased production of gametocytes in the mammal; wherein the composition improves fertility by promoting gametogenesis in the mammal; wherein the composition is provided to the mammal as a daily dose, wherein the daily dose comprises from 1 gram to about 50 gram (g) of the glucosamine component; wherein the mammal is a horse or other large mammal and wherein the daily dose comprises approximately 20 g of the glucosamine component.

Rovati teaches a composition comprising glucosamine sulphate and glucosamine hydrochloride in the form of a tablet, capsule or suppository and formulated for intravenous use.

Schleck teaches a powdered composition comprising glucosamine sulfate sodium chloride (NaCl).

Maier teaches a composition comprising glucosamine sulphate – 2KCl in the form of a tablet, on page 9, under "Example 1".

It is noted that the references do not teach that the composition can be used in the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "such that, when administered to a mammal is an effective amount, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.



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"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The references anticipate the claimed subject matter.

Claims 18-21, 46-51, 57-59, 61 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Watson et al. (D).

Applicant's claimed invention of Claims 18-21 and 46-49 was set forth above. Applicant further claims the composition of claim 50, wherein the nutrient component is selected from the group consisting of an oil cake component, an acid component, a mineral component, a vitamin component, a functional food component, and combinations of these; and, wherein the nutrient component comprises nutrients selected from the group consisting of N-acetyl-D-glucosamine, glutamine, arginine, and combinations of these. Applicant further claims the composition of claim 51, wherein said functional food component further comprises an ingredient selected from the group consisting of prebiotic, probiotic, synbiotic and combinations of these; wherein the selected components are present in the following approximate effective proportions: between about 50 and about 200 pbw oil cake, between about 400 to 750 pbw glucosamine component, between about 50 and about 150 pbw acid component, between about 0.0001 and about 1 pbw mineral component, between about 0.0001

about 1 pbw vitamin component, and between about 0.0001 and about 1 pbw of functional food component. Applicant further claims the composition of claim 61, further comprising a filler.

Watson teaches a composition comprising from about 5 to about 20 weight percent of N-acetylglucosamine; a synbiotic mixture of 20 to about 60 weight percent of a probiotic (functional food component;) and 10 to about 50 weight percent of fructooligosaccharides (functional food component, probiotic for bifidobacteria, thereby a prebiotic); and from about 15 to about 50 weight percent of glutamine (a nutrient, functional food component). See Column 1, line 60 bridging Column 2, line 60. The composition taught by Watson can be mixed together and formulated into tablets or capsules; and may further contain filler. See Column 2, lines 61-67.

It is noted that the reference does not teach that the composition can be used in the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "such that, when administered to a mammal is an effective amount, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable

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distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 18-21, 46-51, 53, 58, 61 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Menard (E).

Applicant's claimed invention of Claims 18-21 and 46-51, 58, 61 and 62.

Applicant further claims the composition of Claim 51, wherein said acid component is ascorbic acid and at least one derivative thereof, lipoic acid, or dihydrolipoic acid, wherein the derivative is selected from the group consisting of magnesium ascorbyl phosphate, sodium ascorbyl phosphate, sodium ascorbate, ascorbyl glucoside, and combinations thereof.

Menard teaches a nutraceutical composition comprising glucosamine sulfate, ascorbic acid (a nutrient acid component) and linoleic acid, wherein the daily dose for

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delivery to a mammal comprises 1500 mg to about 2500 mg of the glucosamine component (glucosamine sulfate). See Column 5, lines 5-65.

It is also noted that the reference does not teach that the composition can be used in the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "such that, when administered to a mammal is an effective amount, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In *re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 18-20, 46-49, 58, 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Allan (F).

Applicant's claimed invention was set forth above.

Allan teaches a composition comprising an effective amount of D-chiro inositol or derivatives thereof, such as glucosamine, for decreasing free and total testosterone levels and/or improving ovulation and/or increasing progesterone and/or sex hormone binding globulin in mammals suffering metabolic diseases such as hyperandrogenism and/or anovulation. See Column 4, lines 5-53. In Column 6, lines 10-64, Allan further teaches the referenced composition in the form of an aqueous solution, tablets, capsules, powders, and granules for oral administration, wherein the effective amount of the active agent administered per dose is the range of about 1 mg/kg/day to 1000 mg/kg/day and wherein the various formulations comprise filler.

It is also noted that the reference does not teach that the composition can be used in each of the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "such that, when administered to a mammal is an effective amount, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as

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a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In *re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 18, 21, 46-49, 58, 61 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by D'Abramo (G).

Applicant's claimed invention of Claims 18, 21, 46-49, 58, 61 and 62 was set forth above. Applicant further claims the composition of claim 51, wherein said mineral component further comprises at least one mineral selected from the group consisting of zinc, boron, chromium, manganese, and combinations thereof; wherein said mineral acid component is further characterized as an amino acid chelate; wherein said vitamin further comprises at least one vitamin selected from the group consisting of biotin, thiamine HCL, folic acid, and combinations thereof.

D'Abramo teaches a composition comprising glucosamine; ascorbylpalmitate; a Vitamin premix including thiamine, folic acid, biotin and ascorbic acid; a mineral premix including zinc and an amino acid chelate, *e.g.*, magnesium oxide.

It is also noted that the reference does not teach that the composition can be used in the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "such that, when administered to a mammal is an effective amount, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency

and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 18, 21, 46-53, 58 and 60-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Meisner (H\*).

Applicant's claimed invention of Claims 18, 21, 46-49, 58, 61 and 62 was set forth above. Applicant further claims the composition of claim 50, wherein the nutrient component comprises between about 50 and about 200 pbw oil cake, between about 400 to 750 pbw glucosamine component, between about 50 and about 150 pbw acid component, between about 0.0001 and about 1 pbw mineral component, between about 0.0001 about 1 pbw vitamin component, and between about 0.0001 and about 1 pbw of functional food component. Applicant further claims the composition of claim 51, wherein the oil cake component is selected from the group consisting of soybean flower, linseed oil cake, cottonseed oil cake, peanut oil cake, safflower oil cake, coconut oil cake, palm oil cake, sesame oil cake, sunflower oil cake, rapeseed oil cake, kapok oil cake, mustard seed oil cake, and combinations thereof.

Meisner teaches a composition, in solid dosage form or liquid dosage form, comprising at least about 10% of an asorbic acid or an ascorbic acid comprising monodehydroascorbic acid, zinc, soy flour, and filler. See patent claims 1, 3-6, 9, 15 and 16.

It is also noted that the reference does not teach that the composition can be used in the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such



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undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "such that, when administered to a mammal is an effective amount, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 18, 20, 21, 46-51 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Abe et al. (U).

Applicant's claimed invention of Claims was set forth above.

Abe teaches a composition comprising copper N-succinyl glucosamate (a glucosamine component and a mineral/functional food component, that is copper), in liquid dosage form, which was administered to mammals for the induction of ovulation in dose amounts of 4 mg/kg/body weight to 10 mg/kg/body weight.

It is also noted that the reference does not teach that the composition can be used in each of the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "such that, when administered to a mammal is an effective amount, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art

does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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